IMV Inc. Announces Breakthrough Data from DeCidE1, its Ongoing Phase 2 Study of DPX-Survivac in Patients with Advanced Recurrent Ovarian Cancer

First in-vivo T cell therapy to demonstrate clinical activity in hard-to-treat solid tumor

79% of evaluable patients achieved disease control on target lesions; 53% experienced tumor regressions

37% achieved durable clinical benefit lasting ≥ 6 months; including four partial regressions so far, overall response rate not yet reached as six patients remain on treatment

Treatment well-tolerated with limited side effects observed

IMV to host a conference call and webcast today, February 25, 2020 at 8:00 a.m. EST; data also to be featured at KOL symposium on Thursday, February 27, 2020

DARTMOUTH, Nova Scotia--(BUSINESS WIRE)-- IMV Inc. (Nasdaq: IMV; TSX: IMV), a clinical-stage biopharmaceutical company pioneering a novel class of immunotherapies, today reported updated results from DeCidE1, an ongoing Phase 2 study of its lead candidate, DPX-Survivac, in patients with advanced recurrent ovarian cancer. The new results show that DPX-Survivac immunotherapy is active and well-tolerated in patients with advanced ovarian cancer.

“Today’s update marks a pivotal milestone for IMV and, we believe, is a breakthrough for targeted T cell immunotherapies, as these results demonstrate for the first time activity in a solid tumor which is among the hardest to treat” said Frederic Ors, President and Chief Executive Officer at IMV. “We were pleased to achieve the primary objectives of our DeCidE1 study, showing DPX-Survivac was active, durable and well-tolerated in advanced ovarian cancer. With these results in hand, we plan to engage with the US Food and Drug Administration (FDA) on the design of a potential pivotal trial in ovarian cancer that might support an accelerated pathway.”

Mr. Ors continued, “Notably, these results also continue to validate the unique mechanism of our DPX platform and the relevance of survivin as a cancer target, as we await updated Phase 2 data from two additional studies of DPX-Survivac in the first half of this year.”

“We are highly encouraged by the data from DeCidE1, which shows that DPX-Survivac immunotherapy was well-tolerated and achieved sustained clinical activity in advanced and recurrent ovarian cancer. This is a particularly significant observation in heavily pre-treated patients, for whom remain tremendous unmet need and limited options beyond single-agent chemotherapy, which generates responses in just 12% of patients with short duration and
severe adverse effects,” said Joanne Schindler, M.D., D.V.M., Chief Medical Officer at IMV. “These results demonstrate DPX-Survivac’s clinical potential as a well-tolerated and, possibly, more effective treatment than currently available therapies. We believe this outcome places DPX-Survivac at the forefront of a new paradigm in the treatment of ovarian cancer and other solid tumors, as a targeted T cell therapy that can achieve durable responses while maintaining quality of life.”

Updated Results from DeCidE1

All 22 patients with advanced recurrent ovarian cancer enrolled in this arm of the study were heavily pre-treated, with the median number of prior therapies greater than three.

As of February 24, 2020, 19 patients were evaluable for efficacy with six patients (31%) still receiving treatment. Key preliminary findings are outlined below:

- 15 patients (79%) achieved disease control, defined as Stable Disease (SD) or Partial Response (PR) on target lesions
  - Tumor shrinkage of target lesions was observed in 10 patients (53%)
- Durable clinical benefits lasting ≥6 months were observed in seven patients (37%) so far:
  - Four of these seven patients (21% of evaluable patients) achieved PR with tumor regression >30% on target lesions
  - Three stable diseases were ongoing for > 6 months (range 7-9) including -29.5% and -12% tumor regressions
  - Median duration not reached yet, with five of these seven (71%) patients still on treatment at > 6 months (range 7-10)
- Analysis of Baseline Tumor Burden (BTB) showed durable clinical benefits across a broad range of BTB (1.5-7.7 cm) with a higher number of patients achieving benefits in BTB < 5 cm as previously observed in other arms of the study:
  - Six out 11 with BTB < 5 cm (55%) achieved clinical benefits lasting > 6 months
- Durable clinical benefits include platinum resistant and refractory patients who previously received PARP inhibitors and bevacizumab
- Treatment was well-tolerated, with most adverse events being Grade 1-2 reactions at the injection site

Clinical Development Plans for DPX-Survivac in Advanced Recurrent Ovarian Cancer and other cancer indications

IMV plans to take these results to the U.S. Food and Drug Administration (FDA) for a Type B meeting, to align on the design of a Phase 2b study with potential to support registration under accelerated approval in this indication.

In parallel, the Company will continue to evaluate DPX-Survivac in other tumor types. Currently, there are two actively accruing Phase 2 studies of DPX-Survivac in combination with Merck’s Keytruda®: SPIReL, an investigator-sponsored study in recurrent/refractory diffuse large B-cell lymphoma (r/r DLBCL) and a basket study across five solid tumor indications. Updated data are expected from both studies in the first half of 2020.

Conference Call and Webcast Information
IMV will host a conference call and webcast on Tuesday, February 25, 2020 at 8:00 a.m. EST to discuss the DPX-Survivac clinical results.

Financial analysts are invited to join the conference call by dialing (866) 211-3204 (U.S. and Canada) or (647) 689-6600 (International). Other interested parties will be able to access the live audio webcast at this link.

The Company also plans to review portions of the data at its upcoming Key Opinion Leader Symposium on Thursday, February 27, 2020 at 8:30 a.m. EST.

Both webcasts will be recorded and available on IMV website for 30 days following under "Events, Webcasts & Presentations."

About the DeCidE1 Study

“DeCidE1” is a Phase 2 multicenter, randomized, open-label study to evaluate the safety and effectiveness of DPX-Survivac with intermittent low dose cyclophosphamide (CPA). This phase 2 arm enrolled 22 patients with recurrent, advanced platinum-sensitive and –resistant ovarian cancer. Patients received 2 subcutaneous injections of DPX-Survivac 3 weeks apart and every eight weeks thereafter, and intermittent low dose CPA one week on and one week off for up to 1 year. Paired tumor biopsies were performed prior to treatment and on treatment.

Primary endpoints of this study are overall response rate, disease control rate and safety. Secondary endpoints include cell mediated immunity, immune cell infiltration in paired biopsy samples, duration of response, time to progression, overall survival and biomarker analyses.

About DPX-Survivac

DPX-Survivac is the lead candidate in IMV’s new class of targeted immunotherapies designed to elicit antigen-specific functional, robust and sustained de novo T cell response. IMV believes this mechanism of action (MOA) is key to generating durable solid tumor regressions. DPX-Survivac consists of five unique HLA-restricted survivin peptides formulated in IMV’s proprietary DPX drug delivery platform and known to induce a cytotoxic CD8+ T cell response against survivin expressing cancer cells.

Survivin, recognized by the National Cancer Institute (NCI) as a promising tumor-associated antigen, is broadly over-expressed in most cancer types and plays an essential role in antagonizing cell death, supporting tumor-associated angiogenesis and promoting resistance to chemotherapies. IMV has identified over 20 cancer indications in which survivin can be targeted by DPX-Survivac.

DPX-Survivac has received Fast Track designation from the U.S. Food and Drug Administration (FDA) as maintenance therapy in advanced ovarian cancer, as well as orphan drug designation status from the U.S. FDA and the European Medicines Agency (EMA) in the ovarian cancer indication.

About IMV

IMV Inc. is a clinical stage biopharmaceutical company dedicated to making immunotherapy more effective, more broadly applicable, and more widely available to people facing cancer
and other serious diseases. IMV is pioneering a new class of immunotherapies based on the Company's proprietary drug delivery platform. This patented technology leverages a novel mechanism of action that enables the programming of immune cells in vivo, which are aimed at generating powerful new synthetic therapeutic capabilities. IMV’s lead candidate, DPX-Survivac, is a T cell-activating immunotherapy that combines the utility of the platform with a target: survivin. IMV is currently assessing DPX-Survivac in advanced ovarian cancer, as well as in a combination therapy in multiple clinical studies with Merck's Keytruda®. Connect at www.imv-inc.com.

IMV Forward-Looking Statements

This press release contains forward-looking information under applicable securities law. All information that addresses activities or developments that we expect to occur in the future is forward-looking information. Forward-looking statements are based on the estimates and opinions of management on the date the statements are made. In the press release, such forward-looking statements include, but are not limited to, statements regarding the FDA potentially granting accelerated regulatory approval of DPX-Survivac and the timing of expected results from other DPX-Survivac’s studies with other tumor types. However, they should not be regarded as a representation that any of the plans will be achieved. Actual results may differ materially from those set forth in this press release due to risks affecting the Corporation, including access to capital, the successful design and completion of clinical trials and the receipt and timely receipt of all regulatory approvals. IMV Inc. assumes no responsibility to update forward-looking statements in this press release except as required by law. These forward-looking statements involve known and unknown risks and uncertainties and those risks and uncertainties include, but are not limited to, our ability to access capital, the successful and timely completion of clinical trials and studies, the receipt of all regulatory approvals and other risks detailed from time to time in our ongoing quarterly filings and annual information form. Investors are cautioned not to rely on these forward-looking statements and are encouraged to read IMV’s continuous disclosure documents, including its current annual information form, as well as its audited annual consolidated financial statements which are available on SEDAR at www.sedar.com and on EDGAR at www.sec.gov/edgar.

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